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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,564	11/14/2003	Orest W. Blaschuk	100086.418	6389

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,564	BLASCHUK ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8,10,11,14-25,39-68 and 94-101* is/are pending in the application.

4a) Of the above claim(s) *3-4, 8, 16-17, 19-25, 39-68 and 94-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,11,14,15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 1/5/07, is acknowledged.

2. Claims 1, 3-4, 8, 10-11, 14-25, 39-68 and 94-101 are pending.

3. Claims 3-4, 8, 16-17, 19-25, 39-68 and 94-101 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 1, 10-11, 14-15 and 18 are under examination as they read on a cell adhesion modulating agent comprises SEQ ID NO:2 or conservative analogue thereof, wherein the peptide present within a linear peptide.

5. In view of the amendment filed on 1/5/07, only the following rejections are remained.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10 and 15 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cell adhesion modulating agent consists essentially of a linear peptide having the amino acid sequence of SEQ ID NO: 2, does not reasonably provide **enablement** any N-terminal or C-terminal modification in claim 10, or the cell adhesion modulating agent that further comprising any "cell adhesion recognistion sequence other than SEQ ID NO:2, separated by a linker in claim 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 7/5/06.

Applicant's arguments, filed 1/5/07, have been fully considered, but have not been found convincing.

Applicants submit that such modifications are illustratively described in the specification and that these and other N- and C-terminal modifications can be readily made and used by the skilled artisan without undue experimentation. For example, at page 66, lines 16 to 23, the specification describes that modulating agents may contain "derivatives of common amino acids, such as amino acids having the C-terminal carboxylate esterified (e.g., benzyl, methyl or ethyl ester) or amidated and/or having modifications of the N-terminal amino group (e.g., acetylation or alkoxycarbonylation), with or without any of a wide variety of side-chain modifications and/or substitutions (e.g., methylation, benzylation, t-butylation, tosylation, alkoxycarbonylation, and the like). Further, the skilled artisan is fully aware of how to confirm that any such modified

peptide modulating agents retain the function of inhibiting cell adhesion, using one or more illustrative assays described in the specification as filed and/or known in the art.

However, given the lack of sufficient guidance and working examples, predicting what changes can be made to the amino acid sequence of SEQ ID NO: 2 that after modification will retain both structure and have similar function as SEQ ID NO: 2 is unpredictable. Because of the unpredictability and the lack of guidance, an undue experimentation would be required to determine which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable. The state of prior art teaches that event a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein/peptide.

Further, Applicant argues that making and using CAR sequence from cell adhesion molecules other than the desmosomal CAR sequence of SEQ ID NO: 2 is extensively described in the specification as originally filed, e.g., at page 60, line 24 to page 63, line 18. As described therein, and as known in the art, CAR sequences have been identified and characterized for a wide variety of cell adhesion proteins. Accordingly, a skilled artisan would understand and expect that a modulating agent of the presently claimed invention may contain, in addition to a CAR sequence consisting essentially of RWAPIP (SEQ ID NO: 2), other CAR sequences and that the use of such other CAR sequences in a claimed modulating agent can serve to further inhibit cell adhesion and/or modulate a function mediated by the cell adhesion protein from which the other CAR sequence was derived.

However, the skilled artisan would not know what other adhesion recognition sequences can be linked to claimed agent and how to use the resultant chimera. It is not clear to the skilled in the art what cell adhesion function can be modulated or inhibited using the resultant chimera.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/10258 (IDS Ref. No. BK).

The '258 publication teaches a compound comprises a region of the desmosomal cadherin (Dsc2) *R***WAPIP**CSML or *R***WAPIP**CSMQ (Dsc3) peptide (see page 4 under Dsc2 and Dsc3 in particular). The two amino acids sequences are Trp-containing and contain no more than 50 consecutive amino acid residues. The two peptide sequences are present within a linear peptide, the compound comprises a peptide which is 10 amino acids (i.e., ranging in size from 6-50/6-15 amino acid residues). The peptide comprises an N-terminal and C-terminal modification. The *R***WAPIP** is lined to a heterologous compound CSML.

The agent of instant claims is included because the agent reads on a compound without a carrier.

While the prior art teachings may be silent as to the "inhibit desmosomal cadherin-mediated cell adhesion" per se; the products the reference are the same as the claimed products. Therefore "inhibit desmosomal cadherin-mediated cell adhesion" is considered inherent properties.

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 1/5/07, have been fully considered, but have not been found convincing.

Applicant argues that the amended claim now drawn to a cell adhesion modulating agent tht inhibits desmosomal cadherin-mediated cell adhesion and consists of essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO. 2). Further, Applicant submits that the claimed compound is not described by the cited prior art. Applicant contends that the prior art teaches a "region" of desmosomal cadherins, but does not teach or suggest modulating agents as claimed, consisting of a linear peptide having the amino acid sequence of SEQ ID NO: 2, much less that such agents can inhibit cell adhesion, as claimed by applicants.

However, the reference teaches a compound consists essentially of a linear peptide having RWAPIP (SEQ ID NO:2). The recitation "consists essentially of a linear peptide *having* the amino acid of SEQ ID NO: 2" is open-ended and would open the claim to include the CSML/CSMQ amino acids (e.g., C-terminal modification).

10. Claims 1 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO94/21809.

'809 publication teaches a compound comprises Thr Val Leu Arg Arg Ala Lys Arg *Arg* **Trp Ala Pro Ile Pro** Cys Ser (see page 47, line 14 in particular). The amino acid sequence is Trp-containing and contain no more than 50 consecutive amino acid residues. The peptide sequence are present within a linear peptide, the compound comprises a peptide which is 16 amino acids (i.e., ranging in size from 6-50 amino acid residues). The peptide comprises an N-terminal and

C-terminal modification. The *R***WAPIP** is linked to a heterologous compound Thr Val Leu Arg Arg Ala Lys Arg *Arg*.

The agent of instant claims is included because the agent reads on a compound without a carrier.

While the prior art teachings may be silent as to the "inhibits desmosomal cadherin-mediated cell adhesion" per se; the products used in the reference are the same as the claimed claimed. Therefore "inhibits desmosomal cadherin-mediated cell adhesion" is considered inherent properties.

The reference teachings anticipate the claimed invention.

Applicant's arguments, filed 1/5/07, have been fully considered, but have not been found convincing.

Applicant argues that the amended claim now drawn to a cell adhesion modulating agent that inhibits desmosomal cadherin-mediated cell adhesion and consists of essentially of a linear peptide having the amino acid sequence Arg-Trp-Ala-Pro-Ile-Pro (SEQ ID NO. 2). Further, Applicant submits that the claimed compound is not described by the cited prior art. Applicant contends that the prior art teaches a 16-mer peptide that comprises a sequence related to SEQ ID NO:2, but does not teach or suggest modulating agents as claimed, consisting of a linear peptide having the amino acid sequence of SEQ ID NO: 2, much less that such agents can inhibit cell adhesion, as claimed by applicants.

However, the reference teaches a compound consists essentially of a linear peptide having RWAPIP. The recitation "consists essentially of a linear peptide *having* the amino acid of SEQ ID NO: 2" is open-ended and would open the claim to include the extra C- and N- amino acids (e.g., N and C-terminal modification).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 10-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK), OR WO94/21809 each in view of in view of U.S. Patent No. 5,455,228 for the same reasons set forth in the previous Office Action mailed 7/5/06.

Applicant's arguments, filed 1/5/07, have been fully considered, but have not been found convincing.

Applicant submits that each WO97/10258 and WO94/21809 fails to teach or suggest the elements of claim 1, for reasons discussed above in the context of the Examiner's rejections under 35 U.S.C. § 102. The '228 patent discusses N-acetylation as a means for inhibiting cleavage by aminopeptidase, but offers nothing in relation to Applicants' claimed modulating agents consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2). Thus, even if a skilled artisan were to N-acetylate a peptide of WO97/10258 or WO94/21809, as described by the '228 patent, the artisan would still not arrive at the invention claimed by Applicants. As both the primary references and the'228 patent fail to teach or suggest the elements of claim 1, or suggest any manner in which the references can be combined to arrive at applicants' claimed subject matter.

Contrary to applicant assertion each of each WO97/10258 and WO94/21809 teaches the compound consists essentially of a linear peptide having the amino acids of SEQ ID NO:2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to N-acytylate the peptide agent taught by the WO `258 or WO94/21809 as taught by the `228 patent to resist cleavage of the peptide by aminopeptidase M.

13. Claims 1 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK) OR WO94/21809 each in view of in view of U.S. Patent No. 6,936,587 for the same reasons set forth in the previous Office Action mailed 7/5/06.

Applicant's arguments, filed 1/5/07, have been fully considered, but have not been found convincing.

Applicant argues that each of WO97/10258 and WO94/21809 fails to teach or suggest the elements of claim 1, for reasons discussed above in the context of the Examiner's rejections under 35 U.S.C. § 102. The '587 patent discusses the attachment of peptides to a solid support for purification purposes, but offers nothing in relation to Applicants' claimed modulating agents consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2). Even to the extent a skilled artisan were to attach a peptide of WO97/10258 or WO94/21809 to a solid support, as described by the '587 patent, the artisan would still not arrive at the invention claimed by Applicants. As both the primary references and the '587 patent fail to teach or suggest the elements of claim 1, or suggest any manner in which the references can be combined to arrive at Applicants' claimed subject matter, the '587 patent does not remedy the deficiencies of the primary references.

Contrary to applicant assertion each of each WO97/10258 and WO94/21809 teaches the compound consists essentially of a linear peptide having the amino acids of SEQ ID NO:2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to link the peptide taught by the WO `258 or WO94/21809 to a solid support as taught by the `587 patent to enrich or purify specific antibodies as taught by the `587 patent.

14. Claims 1 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/10258 (IDS Ref. No. BK), OR WO94/21809 each in view of in view of U.S. Patent No. 6,713,450 for the same reasons set forth in the previous Office Action mailed 7/5/06.

Applicant's arguments, filed 1/5/07, have been fully considered, but have not been found convincing.

Applicant submits that Each of WO97/10258 and WO94/21809 fails to teach or suggest the elements of claim 1, for reasons discussed above in the context of the Examiner's rejections under 35 U.S.C. § 102. The '450 patent discusses the formulation of a peptide in carriers, excipients and the like, but offers nothing in relation to Applicants' claimed modulating agents consisting essentially of a linear peptide having the sequence RWAPIP (SEQ ID NO: 2). Thus, even to the extent a skilled artisan were to formulate a peptide of WO97/10258, Chidgey et al. or WO94/21809 in a manner described by the '450 patent, the artisan would still not arrive at the invention claimed by Applicants. As both the primary references and the'450 patent fail to teach or suggest the elements of claim 1, or suggest any manner in which the references can be combined to arrive at Applicants' claimed subject matter, the '450 patent does not remedy the deficiencies of the primary references. Reconsideration is respectfully requested.

Contrary to applicant assertion each of each WO97/10258 and WO94/21809 teaches the compound consists essentially of a linear peptide having the amino acids of SEQ ID NO:2. to formulate the peptide agent taught by the WO `258 or WO94/21809 into a composition using pharmaceutically-acceptable carriers as taught by the `450 patent because such formulations are readily determined by one of ordinary skill in the art and include formulations for immediate release and for sustained release as taught by the `450 patent.

15. No claim is allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 14, 2007

Maher Haddad

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